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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,534	04/09/2007	Takuji Nishide	83363.0015	3794

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EXAMINER

HOLLOWAY, IAN KNOBEL

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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03/04/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/576,534	Applicant(s) NISHIDE ET AL.	
	Examiner IAN K. HOLLOWAY	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/7/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed (12/7/09). Claims 5 and 6 has been canceled without prejudice. Claims 1-4, and 7-20 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Douk (US Pg Pub 2005/0027236)**, herein after referred to as **D**, in view of

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Noriega et al. (US Pg Pub 2005/0119615), herein after referred to as **N and Schwager (US Pg Pub 2001/0007922)**, herein after referred to as **S**.

Regarding **Claim 1**, D discloses a guidewire shaft (**112**, guidewire shaft) disposed at the distal region of the distal shaft, the guidewire shaft having a guidewire lumen into which a guidewire is insertable, the guidewire lumen being disposed in the guidewire shaft; a hub (**120**, hub) provided at the proximal end of the proximal shaft, the aspiration lumen extending to the hub;

D fails to disclose the proper main shaft and a detachable core wire disposed in the aspiration lumen.

However, S teaches a main shaft including a distal shaft (8) and a proximal shaft, (3) wherein an aspiration lumen (4, this lumen is capable of performing this task) for removing the substance by aspiration is disposed in the distal shaft and the proximal shaft; a detachable core wire (70, the independent wire) disposed in the aspiration lumen: wherein the relationship $0.4 < R1/R2 < 0.7$ is satisfied, wherein R1 is a maximum outer diameter of the core. wire, and R2 is a minimum inner diameter of the aspiration lumen located on the distal side of the hub.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the wire separable, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the wire diameter the proper size, since it has been held

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that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

However, **N** teaches a detachable core wire (**22**, drive shaft) disposed in the aspiration lumen.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the core as taught by **N**, since **N** states at paragraph 78 that such modification would allow for the crossing of lesions. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **N**, to improve the device of **D** for the predictable result of making it more mobile.

Regarding **Claim 2**, **N** discloses: a connector (**21**, the handle) is fixed on the proximal end of the core wire, and the connector is mounted to the proximal end of the hub in a detachable manner.

Regarding **Claim 3**, **N** discloses: the interior of the aspiration lumen can be flushed through the connector with the connector being mounted to the proximal end of the hub in a detachable manner. (**Fig. 3A**, the core does not interfere with the lumen).

Regarding **Claim 4**, **N** discloses: the distal end of the core wire recedes from the distal end of the aspiration lumen in the proximal direction. (**Fig. 3**, the tip narrows).

Regarding **Claim 7**, **N** discloses: the core wire is a spring wire comprising a coiled metal wire. (**34**, coiled wire).

Regarding **Claim 8, N** discloses: at least a portion of the core wire has a tapered shape (**Fig. 3**, the end tapers) in which the outer diameter becomes larger toward the proximal end..

Regarding **Claim 9, N** discloses: at least a portion of the core wire has flexibility which becomes higher toward the distal end. (**Paragraph 10**).

Regarding **Claim 10, N** discloses: the core wire comprises stainless steel, a Co-Cr alloy, an Ni-Ti alloy, an Ni-Ti-Fe alloy, an Ni-Ti-Cu alloy, an Ni-Ti-Cr alloy, an Ni-Ti-V alloy, an Ni-Ti-Co alloy, an Ni-Ti-Nb alloy, an Ni-Ti-Pd alloy, an Ni-Ti-Cu-Cr alloy, or a composite thereof. (**Paragraph 80**).

Regarding **Claims 11 and 12, D** discloses: the invention as claimed above except for the proper L relationship.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the proper range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding **Claim 13, N** discloses: a radiopaque marker. (**36**, radiopaque marker).

Regarding **Claim 14, D** discloses: a polyimide. (**Paragraph 27**).

Regarding **Claim 15, N** discloses: a braided tube (**Fig. 10**, braid and polymer) in which a metal braid and a polymer material are combined.

Regarding **Claim 16, N** discloses: an inner layer (**Fig. 3A**) defining the aspiration lumen, a metal braid disposed on the outer surface of the inner layer, and an outer layer disposed on the outer surface of the metal braid.

Regarding **Claim 17, D** discloses: the invention as claimed above except for the proper flexural modulus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the flexibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 19 D discloses the steps of inserting the aspiration catheter into a living body with the core wire being present in the aspiration lumen, then withdrawing the core wire, and applying a negative pressure to the aspiration lumen to remove by aspiration a substance from the living body(**Paragraph 45-47**)

Regarding claim 20, N discloses the core wire has a straight shape (Fig 2, the wire is straight)

4. Claim 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **D and N**, in view of Ha et al. (US Patent 6159195).

Regarding **Claim 18, D** discloses the invention claimed above except for the coating.

However H teaches at least a portion of the distal shaft is applied with a hydrophilic coating (**Column 6, lines 13-19**, hydrophilic coating well known in the art) that exhibits a lubricating property in a wet environment.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the coating since it was known in the art that coatings are commonly applied.

Applicant's arguments filed 12/7/09 have been fully considered but they are not persuasive.

Response to Arguments

Applicant states, the amended claims differentiate over the prior art, however, the claims remain rejected as seen from the examples above.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN K. HOLLOWAY whose telephone number is (571)270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ian K Holloway/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763